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APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY. DOCKET NO. 08/482,283 06/07/95 THOMPSON HM11/1023 PAPER NUMBER M PAUL BARKER FINNEGAN HENDERSON FARABOW **GARRETT & DUNNER** 1300 I STREET NW WASHINGTON DC. 20005 10/23/98 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed or This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** is/are pending in the application. 🔀 Claim(s) is/are withdrawn from consideration. Of the above, claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction or election requirement. Claim(s) **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on is/are objected to by the Examiner. is approved disapproved. The proposed drawing correction, filed on The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of Reference Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftperson's Patent Drawing Review, PTO-948

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Notice of Informal Patent Application, PTO-152

Part III: Detailed Office Action

Claims 22-25 and 37-40 are under consideration.

The Examiner notes the amendment of the priority claim in this application. Accordingly, the previous rejections of Claims 22-25 under 35 U.S.C. 102(a) as being anticipated by Hannum et al. (U) and under 35 U.S.C. 102(a) as being anticipated by Eisenberg et al. (V) are withdrawn.

Formal Matters:

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The new title of the invention is acknowledged.

The Information Disclosure Statement filed 12/14/99 could not be completely considered as, contrary to what was stated on the submission, no references accompanied the submission. At this time, only reference EP 0 341 273 B1, which was cited in a related case, and the cited US patents have been considered. If, in fact, the references WERE submitted, and applicants can substantiate such, applicants are invited, in response to this Office Action, to resubmit such, or to direct the Examiner as to in which other application such may be found; they will then be considered as if they had been filed on 12/14/99.

Drawings

The drawings are objected to as failing to comply with 37 37 C.F.R. § 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In Figure 6 and Figure 7, the chromatographic peaks are given number 1-18 and 1-7, respectively, but these reference numbers are not mentioned in the description. Correction is required.

The drawings are objected to because in Figure 4A, the text is upside down. Correction is required.

Figures 4, 13, and 15 of the instant application are presented on multiple separate panels. 37

C.F.R. § 1.84 (u)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84 (u)(1), Applicant is required to change the Brief Description of the Drawings and the rest of the specification accordingly (see p. 42, line 20; p. 17, line 8; p. 18, line 17; and p. 18, line 24). If, for example, Figure 4 is divided into Figures 4A and 4B, then the Brief Description and all references to this figure in the specification must refer to Figures 4A and/or 4B. While all drawings except are correctly numbered, e.g., Figure 4A, Figure 4B, the description of the drawings does not correspond.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 37 C.F.R. § 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed alterations have been made to the oath or declaration. See 37 37 C.F.R. § 1.52(c) and 1.57).

The Residence and Country of Citizenship of inventor R.C. Thompson have been altered without initialing.

New Matter:

The amendment filed 11/26/97 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Figures 20-64, added by amendment in paper #10.

Applicant is required to cancel the new matter in the response to this Office action.

It is noted that in paper number 10, applicants alleged that the introduction of the drawings

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did not constitute new matter due to the incorporation by reference of parent application 07/555274. However, careful review of the first paragraph of the instant specification reveals that while priority to that application was claimed, there is no incorporation by reference to such. Even if such had been incorporated by reference, to be proper, such an incorporation would have had to specifically refer to what matter was being so incorporated. Accordingly, the Figures constitute new matter.

The amendment filed 5/7/99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: There is not basis in the specification as filed for the insertion at page 25 line 12, nor is there a proper incorporation of such by reference to U.S. Patent Number 5,075,222.

Applicant is required to cancel the new matter in the response to this Office action.

Double Patenting Rejections:

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 37 C.F.R. § 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 37 C.F.R. § 3.73(b).

Claim 22 remains, and newly introduced claims 37-39 are rejected under the judicially created doctrine of double patenting over claim 1 in view of 4 of prior U.S. Patent No. 5,075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98, at page(s) 4.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

Claims 23-25 remain, and claim 40 is rejected under the judicially created doctrine of double patenting over claims 11 and 17 of U. S. Patent No. 5, 075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98, at page(s) 4-5. It is noted that claim 4 of the patent states that the DNA includes nucleotides 99-554 of the sequence listed therein; that sequence plus a methionine codon (or the additional two bases of one), which would be obvious to include as a person of ordinary skill in the art would have known that such is required for translation (production) of the encoded protein, would meet the limitations of claim 40.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

Claims 24 and 25 remain rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 5,453, 490 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons cited in the previous Office Action, mailed 1/30/98, at page(s) 5-6.

Applicants intent to file a terminal disclaimer to overcome this rejection is noted.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out

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his invention.

Claims 22-23 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the specification as originally filed for a recitation of nucleic acids encoding an amino acid sequence 70% (or 80% or 90% or 95%) homologous to that of claim 22. This is a new matter rejection.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, Ph.D., can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D. Primary Examiner

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